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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/042,488	03/16/1998	RONALD M. EVANS	SALK1520-2	5034

7590

01/06/2003

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EXAMINER

KAUSHAL, SUMESH

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 01/06/2003

41

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/042,488

Applicant(s)

EVANS ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1, 3-9, 11-13, 15-24, 39-40, 47-55 and 57-77.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
JEFFREY FREDMAN  
PRIMARY EXAMINER

Art Unit: 1636

Continuation Sheet (PTO-303)

Continuation of 2. NOTE: The newly introduced claim limitation "wherein said response element (a) has about 12-20 base pairs (b) binds to said modified ecdysone receptor and (c) does not bind to farnesoid X receptor (FXR)" would require further consideration and/or search under 35 USC 112(1) regarding written description and enablement issues. In addition the newly introduced claim limitation "nuclear receptor" would also requires further consideration and/or search under 35 USC 112(1) regarding written description and enablement issues.

Claims 72-77 stand rejected under 35USC 112(1) regarding enablement issues for the same reasons of record as set forth in the office action mailed on 08/13/02. The subject matter of instant claims encompass a method of modulating the expression of an exogenous gene in a mammalian subject, which clearly falls in the realm of gene therapy. The applicant argues that the DNA constructs contemplated for use in such methods are analogous to the methods of use employing isolated cells. However, this is not found persuasive for the same reasons of record as set forth in the office action mailed on 08/13/02 (see pages 9-10). The earlier office action clearly provided evidence that the gene therapy is considered highly experimental area of research at this time, and both researchers and the public agree that demonstrable progress to date has fallen short of initial expectations. Since the modulation of gene expression in vivo by administering to a target cell an ecdysone responsive system (as claimed) is not consider routine in the art and without sufficient guidance to a specific therapeutic gene the experimentation left to those skilled in the art would be unnecessarily, and improperly, extensive and undue.